Please rewrite claims 1, 5, 9, 43, 51, 59 and 64 as follows:

-- 1. (Amended) A pharmaceutical formulation comprising (I) an inner solid particulate phase, and (2) an outer solid continuous phase in which particles of the inner solid particulate phase are dispersed and embedded, the particles of the inner solid particulate phase comprising (a) a pharmaceutical having a high water solubility selected from metformin or a pharmaceutically acceptable salt thereof; and (b) an extended release material, and the outer solid continuous phase comprising an extended release material, wherein the total extended release material content in both the inner solid particulate phase and the outer solid continuous phase is within the range more than about 30% by weight of the pharmaceutical formulation.--

-- 5. (Amended) The pharmaceutical formulation as defined in Claim 1 wherein the pharmaceutical is metformin hydrochloride.--

-- 9. (Amended) The pharmaceutical formulation as defined in Claim 1 which when ingested by a human reduces maximum attained plasma-metformin concentration (Cmax) by at least about 15% (relative to marketed rapid-release metformin formulations), and increases time to reach maximum metformin-plasma concentration (Tmax) by at least about 30% (relative to marketed rapid-release metformin formulations), while having an insignificant effect on area under the plasma-metformin concentration time curve (AUC) and % urinary recovery (UR) of the dose of metformin (relative to marketed rapid-release metformin formulations).--

-- 43. (Amended) A pharmaceutical formulation comprising (I) an inner solid particulate phase, and (2) an outer solid continuous phase in which particles of the inner solid particulate phase are dispersed and embedded, the particles of the inner solid particulate phase comprising (a) metformin; and (b) an extended release material, and the outer solid continuous phase comprising an extended release material, wherein the extended release material present in the inner solid particulate phase is different from the extended release material present in the outer solid continuous phase and wherein the total extended release material content in both the inner solid particulate phase and the outer solid continuous phase is within the range from about 25 to about 75% by weight of the pharmaceutical formulation.--

-- 51. (Amended) The pharmaceutical formulation as defined in Claim 43 wherein the metformin is metformin (2:1) fumarate.--

-- 59. (Amended) The pharmaceutical formulation as defined in Claim 43 further including another antihyperglycemic agent and/or a hypolipidemic agent.--

-- 64. (Amended) The pharmaceutical formulation as defined in Claim 43 which when ingested by a human reduces maximum attained plasma-metformin concentration (Cmax) by at

least about 15% (relative to marketed rapid-release metformin formulations), and increases time to reach maximum metformin-plasma concentration (Tmax) by at least about 30% (relative to marketed rapid-release metformin formulations), while having an insignificant effect on area under the plasma-metformin concentration time curve (AUC) and % urinary recovery (UR) of the dose of metformin (relative to marketed rapid-release metformin formulations).--

A8 Cont

REMARKS

This amendment is being filed in response to the Official Action mailed in this application on March 26, 2001. A request for an extension of time accompanies this amendment. Also accompanying this amendment is an information disclosure statement (including fee letter). By this amendment, a typographical error was corrected in the specification. (Two of the digits in an amount given in example 3 were transposed.) Also by this amendment, claims 3, 16, 17, 25, 42, 50 and 71 were canceled without prejudice. Finally, claims 1, 5, 9, 43, 51, 59 and 64 were amended. Claim 1 was amended to limit the pharmaceutical having a high water solubility to metformin or a pharmaceutically acceptable salt thereof; and claims 5, 9, 43, 51, 59 and 64 were amended to change the claims' dependencies after canceling other claims. Accordingly, no new matter has been added by this amendment, and claims 1, 2, 4-15, 18-24, 26-41, 43-49 and 51-70 remain pending in this application (although claims 34-41 and 65-70 stand withdrawn from consideration). Reconsideration of this application is respectfully requested in view of the above amendments and further in view of the following remarks.

First, applicants note that PTO forms 1449 sent with their information disclosure statements when this application was filed have not been initialed and returned by the Examiner. Applicants request that these forms, and the form submitted with the information disclosure statement accompanying this amendment, be returned with the next correspondence from the Examiner.

Turning to the action, applicants note that the requirement for restriction has been maintained. Once again, applicants request that the requirement be reconsidered.

Next, claims 1-33, 42-64 and 71 were rejected under 35 U.S.C. §103 as being unpatentable over WO 96/08243 taken together with either Chemical Abstract 132:83528 or Chemical Abstract 126:229547 or the Pentikäinen article. Applicants respectfully traverse this rejection.

The first sentence of the rejection asserts that the claims specify a general "biphasic release rate", implying that there are two rates of drug release. Applicants would like to clarify that they are not claiming two rates of drug release. Rather, the claims refer to a novel mode of construction, that is, a formulation having an external continuous phase (a first phase) and an inner solid

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